INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Compl	ete if Known
Application Number	10/541,195
Filing Date	June 30, 2005
First Named Inventor	Patricia SALVATI
Group Art Unit	1617
Examiner Name	Sahar JAVANMARD
Confirmation No.	7746
Attorney Docket No.	373987-004US (396982)

	an.	I monin	T) :	Name of Patentee or Applicant of Cited Document		
Examiner Initials*	Cite No. ¹	U.S. Publication	Kind Code (if known)		Date of Publication of Cited Document MM-DD-YYYY	
	A1	US-3,549,690		Leigh et al.	12-22 -1970	
	A2	US-3,576,864		Nagarajan	04-27-1971	
	А3	US-3,658,967		Leigh et al.	04-25-1972	
	A4	US-4,049,663		Harper et al.	09-20-1977	
	A5	US-4,267,354		Krapcho et al.	05-12-1981	
	A6	US-4,311,853		Cree et al.	01-19-1982	
	A7	US-4,513,009		Roques et al.	04-23-1985	
	A8	US-4,631,287		Chakraborty et al.	12-23-1986	
	A9	US-4,639,468		Roncucci et al.	01-27-1987	
	A10	US-4,725,608		Nakaguchi et al.	02-16-1988	
	A11	US-4,725,619		Chakraborty et al.	02-16-1988	
	A12	US-4,839,369		Youssefyeh et al.	06-13-1989	
	A13	US- 4,927,835		Kise et al.	05-22-1990	
•	A14	US-4,927,836		Holloway et al.	05-22-1990	
	A15	US-5,236,957		Dostert et al.	08-17-1993	
	A16	US-5,391,577		Dostert et al.	02-21-1995	
	A17	US-5,446,066		Varasi et al.	08-29 -1995	
•	A18	US-5,449,692		Varasi et al.	09-12-1995	
	A19	US-5,475,007		Cai et al.	12-12-1995	
<u>.</u>	A20	US-5,482,964		Hays	01-09-1996	
	A21	US-5,498,610		Chenard	03-12-1996	
	A22	US-5,502,079		Dostert et al.	03-16-1996	

Examiner	Date Considered	
Signature	Date Collidered	

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 A23	US-5,670,546	Park et al.	09-23-1997
A24	US-5,688,830	Berger et al.	11-18-1997
 A25	US-5,723,489	Sher et al.	03-03-1998
 A26	US-5,741,818	Dimmock	04-21-1998
 A27	US-5,849,737	Chaplan et al.	12-15-1998
 A28	US-5,945,454	Peverello et al.	08-31-1999
 A29	US-6,281,211	Cai et al.	08-28-2001
A30	US-6,303,819	Peverello et al.	10-16-2001
A31	US-6,479,484	Lan et al.	11-12-2002
A32	US-6,500,825	Lan et al.	12-31-2002
A33	US-7,091,210	Lan et al.	08-15-2006
 A34	US-RE40,259	Pevarello et al.	04-22-2008
 A35	US 2004/0248978	Salvati	12 09 2004
A36	US-2007/0093495	Ruggero et al.	04-26-2007
A37	US-2007/0203182	Besana et al.	08-30-2007
 A38	US-2008/096965	Barbanhti et al.	04-28-2008

Examiner	Cite	Fo	FOR reign Patent Docu		Date of	JMENTS	Transla	ıtion²
Initials*	No.	Office	Number	Kind Code (if known)	Publication of Cited Document MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Yes	No
	B1	EP	0200101	A2	12-10-1996	USV Pharmaceutical Corp.		
	B2	EP	0415143	Al	03-06-1991	Warner-Lambert Co.		
-	В3	EP	0 525 360	A2	02-03-1993	Korea Research Institute of Chemical Technology		
	B4	GB	1140748		01-22-1969	Imperial Chemical Industries, Ltd		

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Sheet	3	of	7	Attorney Docket No.	373987-004US (396982)

B5	GB	2059963	Α	04-29-1981	A.H. Robins Co., Inc.	
 B6	wo	90/14334		11-29-1990	Farmitalia Carlo Erba S.R.L.	
В7	wo	94/22808		10-13-1994	Pharmacia/Farmitalia Carlo Erba SRL	
B8	WO	94/22809		10-13-1994	Pharmacia/Farmitalia Carlo Erba	
В9	WO	96/40628		12-19-1996	The University of Saskatchewan	
B10	wo	97/05102		02-13-1997	Pharmacia & Upjohn S.p.A.	
B11	wo	97/05111		02-13-1997	Pharmacia & Upjohn S.p.A.	
B12	wo	98/19998		05-14-1998	Novartis AG	
B13	wo	98/25594		06-19-1998	SmithKline Beecham PLC	
B14	wo	98/43964		10-08-1998	Pharmacia & Upjohn S.p.A.	
 B15	wo	98/47869		10-29-1998	CoCensys, Inc.	
B16	wo	99/26614		06-03-1999	CoCensys, Inc.	
B17	wo	99/35123		07-15-1999	Newron Pharmaceuticals SpA	
B18	wo	99/35125		07-15-1999	Newron Pharmaceuticals SpA	
B19	wo	99/39712		08-12-1999	CoCensys, Inc.	
B20	wo	00/61188		10-19-2000	CoCensys, Inc.	

Complete if Known

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1617

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Sahar JAVANMARD

Application Number

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Group Art Unit

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Examiner Initials*	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s),			
	No.	volume-issue number(s), publisher, city and/or country where published.		No	
	C1	Anonymous, "Cambridge NeuroScience's grant for channel blockers," SCRIP World Pharmaceutical News 1870:8 (1993)			
	C2	Anonymous, "Neurogen Licenses National Institutes of Health (NIH) anticonvulsants," SCRIP World Pharmaceutical News 1773:14 (1992)			
	С3	AWOUTERS (ed.), Proceedings, XIVth International Symposium on Medicinal Chemistry, Maastricht, The Netherlands, 8 - 12 September 1996, Elsevier Science B.V. (Amsterdam), (cover, front matter, table of contents, index of authors, subject index, Stanford University Libraries date stamp). Copyright 1997; date stamped 24 August 1998, Swain Library, Stanford University.			
	C4	Bensimon, G., et al., "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," New Engl. J. Med. 330:585-591 (1994)			

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Complete if Known Substitute for form 1449A/PTO 10/541,195 Application Number June 30, 2005 Filing Date INFORMATION DISCLOSURE First Named Inventor Patricia SALVATI STATEMENT BY APPLICANT 1617 **Group Art Unit** Examiner Name Sahar JAVANMARD (Use as many sheets as necessary) Confirmation No. 7746 7 Attorney Docket No. 373987-004US (396982) of Sheet

	C5	Brown, C.M., et al., "Neuroprotective properties of Lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," British J. Pharmacol. 115:1425-1432 (1995)		
	C6	Catterall, W.A., "Common modes of drug action on Na ⁺ channels: Local anesthetics, antiarrhythmics and anticonvulsants," <i>Trends Pharmacol. Sci.</i> 8:57-65 (1987)		
	C 7	Catterall, W.A., "Neurotoxins that Act on Voltage-Sensitive Sodium Channels in Excitable Membranes," Ann. Rev. Pharmacol. Toxicol. 20:15-43 (1980)		
-	C8	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," Science 242:50-61 (1988)		
	С9	Complaint, Civil Action No. 1:07-cv-00487 (March 12, 2007)		
	C10	Denicoff, K.D., et al., "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," J. Clin. Psychiatry 55:70-76 (1994)		
	C11	Decision, Preliminary Motions, Bd.R. 125, interference no. 105,394 (2007)	-	
	C12	Dimmock, J.R., et al., "(Aryloxy)aryl Semicarbazones and Related Compounds: A Novel Class of Anticonvulsant Agents Possessing High Activity in the Maximal Electroshock Screen," J. Med. Chem. 39:3984-3997 (1996)		
	C13	Dostert et al., "New anticonvulsants with selective MAO-B inhibitory activity," European Neuropsychopharmacology, 1(3):317-319 (September 1991)		
	C14	ELRIFI et al., "Request for ex parte reexamination of U.S. patent no. 6,479,484 B1," filed July 2, 2003 on behalf of Newron Pharmaceuticals, SpA		
	C15	FARIELLO et al., "Preclinical evaluation of PNU-151774E as a novel anticonvulsant," J. Pharmacol. Exp. Ther. 285(2):397-403 (May 1998)		
	C16	Faravelli L. et al., "NW 1029 is a novel na+ channel blocker, with analgesic activity in animal models." Abstract, Annual Meeting, Society for Neuroscience 2000; 26 (1):1218		
	C17	Fields, "Peripheral neuropathic pain: an approach to management," in PD Wall and R Melack (eds.), Textbook of Pain, 3 rd ed., Churchill Livingstone, pp. 991-996 (1994)		
	C18	(First) Declaration of Robert A. McArthur, Pevarello Exhibit 2036, interference 105,394 (2006)		
	C19	First Declaration of Stephen G. Waxman, M.D., Ph.D., PX 2003, interference no. 105,394 (2006)		
	C20	Galer BS, "Neuropathic pain of peripheral origin: advances in pharmacologic treatment," Neurol. 45:S17-S25, 1995		
	C21	Guieu et al., "Central analgesic effect of valproate in patients with epilepsy," Seizure 2:147-150 (1993)		

Examiner	Date Considered	
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1617

Patricia SALVATI

Sahar JAVANMARD

Application Number

First Named Inventor

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Examiner Name

Filing Date

C22	Graham, S.H., et al., "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW 619C89, in Rat Middle Cerebral Artery Occlusion," J. Pharmacol. Exp. Ther. 269:854-859 (1994)	
C23	Hammer et al., "Effect of Riluzole on acute pain and hyperalgesia in humans," Brit. J. Anaesthesia 82(5):718-22 (1999)	
C24	International Search Report for PCT/EP03/12889 dated Feb. 3, 2004.	
C25	Judgment, Preliminary Motions, Bd.R. 127, interference no. 105,394 (2007)	
C26	Kingery, "A critical review of controlled clinical trials for peripheral neuropathic pain and complex regional pain syndromes," <i>Pain</i> 73:123-139 (1997)	
C27	Lunardi et al., "Clinical effectiveness of lamotrigine and plasma levels in essential and symptomatic trigeminal neuralgia," Neurology 48(6):1714-1717 (1997)	
C28	Magnus L., "Nonepileptic uses of gabapentin experience, <i>Epilepsia</i> , 1999; 40 (Suppl. 6) S66-72; discussion 873-874	
C29	Mathew, Ninan T., "Pathophysiology, epidemiology and impact of Migraine" Clinical Cornerstone, vol. 4, no. 3, 2001, pages 1-17	
C30	May et al., "The trigeminovascular system in humans: pathophysiologic implications for primary headache syndromes of the neural influences on the cerebral circulation," J. Cereb. Blood flow Metab., vol. 9,1999, pages 115-127	
C31	McQuay et al., "Anticonvulsant drugs for management of pain: a systematic review," BMJ 311:1047-1052 (21 October 1995)	
C32	Memorandum Opinion and Order, interference no. 105,394 (2007)	
C33	Nakamura-Craig et al., "Effect of lamotrigine in the acute and chronic hyperalgesia induced by PGE ₂ and in the chronic hyperalgesia in rats with streptozocin-induced diabetes," Pain 63:33-37 (1995)	
C34	Notice Of Dismissal With Prejudice, Civil Action No. 1:07-cv-00487 (July 25, 2007)	
C35	Official action, counterpart Brazilian application (to RE40,259) no. PI 9814548-7 (translation)	
C36	Peitl B. et al., "Capsaicin-insenBitive sensory-efferent meningeal vasodilatation evoked by electrical stimulation of trigeminal nerve fibres in the rat," British Journal of Pharmacology (1999) 127, 457-467.	
C37	Pevarello et al., "Synthesis and Anticonvulsant Activity of a New Class of 2-[(Arylalkyl)amino]alkanide Derivatives", J. Med. Chem. 41:579-590 (1998)	
C38	PEVARELLO et al., "Stereoselectivity, sigma binding and sodium channel blocking activity of 2-amino propanamide anticonvulsants." (3 pages) (September 12, 1996).	
C39	Puig et al., "Formalin-evoked activity in identified primary afferent fibers: systemic lidocaine suppresses phase-2 activity," Pain 64:345-355 (1995)	

Examiner	 Date Considered	
Signature	 Date Considered	

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C40	Reuter U. et al., 'Experimental models of migraine", Functional neurology (15) Suppl. 3 9-18, 2000	
C41	SALVATI et al., "Anticonvulsant profile of FCE26743A (PNU-151774), a novel 2- aminopropionamide derivative. Society for Neuroscience. Washington. Nov 15 - 21, 1996." (4 pages) (November 21, 1996, date solely for purpose of initial consideration)	
C42	Saxena et al: "Pharmacology of antimigraine drugs," Journal of Neurology, 1991, pages S28-S35	
C43	Shibata et al., "Modified formalin test: characteristic biphasic pain response," Pain 38:347-352 (1989)	
C44	Steiner et al: "Lamotrigine versus placebo in the prophylaxis of migraine with and without aura" Cephalgia, vol. 17, 1997, pages 109-112	
C45	Stys, P.K., et al., "Ionic Mechanism of Anoxic Injury in Mammalian CNS White Matter: Role of Na, Channels and Na ⁺ -Ca ²⁺ Exchanger," J. Neurosci. 12:430-439 (1992)	
C46	Supplemental data, Vieth et al., "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," J. Med. Chem. 47:224-232 (2004) (downloaded August 20, 2007 from http://pubs.acs.org) (excerpted fields)	
C47	Tanelian et al., "Neuropathic pain can be relieved by drugs that are use-dependent sodium channel blockers: lidocaine, carbam azepine, and mexiletine," Anesthesiol. 74(5):949-951 (1991)	
C48	Tanclian et al., "Sodium channel-blocking agents: their use in neuropathic pain conditions," Pain Forum 4(2):75-80 (1995)	
C49	Taylor, C.P. and Meldrum, B.S., "Na [†] channels as targets for neuroprotective drugs," Trends Pharmacol. Sci. 16:309-316 (1995)	
C50	Tjolsen et al., "The formalin test: an evaluation of the method," Pain 51:5-17 (1992)	
C51	Vaghi et al., "Neuroprotective effect of PNU-151774E, a new anticonvulsant compound, in the model of global ischaemia in gerbils." (5 pages) (October 30, 1997, date solely for purpose of initial consideration)	
C52	Varasi et al., "Synthesis and anticonvulsant activity of new benzyloxybenzylacetamide derivatives," from Abstracts, XII th International Symposium on Medicinal Che mistry, Basel, Switzerland, September 13-17, 1992 (2 pages) (1992)	
C53	Varasi et al., "Synthesis and anticonvulsant activity of new benzyloxybenzylacetamide derivatives" (2 pages) (1992)	
C54	Vieth et al., "Characteristic Physical Properties and Structural Fragments of Marketed Oral Drugs," J. Med. Chem. 47:224-232 (2004)	
C55	Webber, "Observations under article 115 EPC", filed November 19, 2002 in EP 98958114.5 (EP 1032377) on behalf of Newron Pharmaceuticals, SpA	

Examiner	Data Canaidanad	
Signature	Date Considered	

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			**	Confirmation No.	7746	
Sheet	7	of	7	Attorney Docket No.	373987-004US (396982)	

Wenzel et al: "Migraine headache misconceptions: barriers to effective care" Pharmacotherapy, vol. 24, no. 5, 2004, pages 638-648			
C57	Wilton, "Tegretol in the treatment of diabetic neuropathy," S. Afr. Med. J. 48(20):869-872 (1974)		
C58	Woolf et al., "The systemic administration of local anaesthetics produces a selective depression of C-afferent fibre evoked activity in the spinal cord," Pain 23(4):361-374 (1985)		

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